NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NAUTILUS NEUROSCIENCES, INC., et al.,	:	**Civil Action Nos. 11-1997 (ES) (SCM)**
Plaintiffs,	:	
v.	:	
WOCKHARDT USA LLC, et al.	:	**OPINION AND ORDER**
Defendants.	:	

WALDOR, United States Magistrate Judge

Before the Court is Defendants' Wockhardt USA, LLC and Wockhardt, Ltd. (collectively "Defendants") application for leave to amend their invalidity contentions. Specifically, Defendants seek to amend their invalidity contentions under L. Pat. R. 3.7: (1) "to incorporate prior art from Defendants' second contentions into its first contentions; (2) to add a claim of indefiniteness under 35 U.S.C. § 112 ¶ 2; and (3) to include recently discovered evidence relating to potential prior art under 35 U.S.C. § 102." (Joint Letter, p. 2) (later defined). Plaintiffs Nautilus Neurosciences, Inc. and APR Applied Pharma Research SA (collectively "Plaintiffs") oppose Defendants' application in its entirety. (Id., p. 6–9.)

Defendants first raised the issue of seeking leave to amend their invalidity contentions with the Court by letter dated September 6, 2012 in advance of the

September 10, 2012 conference. (Dkt. No. 74; "September 6th Letter"). Following the conference, the Court asked the parties to submit a joint letter detailing their positions with respect to Defendants' requested amendments, which they did by letter dated September 21, 2012 ("Joint Letter"). After telephone conferences on both October 2 and 5, 2012, the parties were asked to present additional separate submissions to the Court regarding Defendants' proposed amendment to add prior art references, which they did on October 19, 2012 ("October 19th Submissions;" see also Dkt. No. 89).[1] After a review of the aforementioned submissions, for the reasons stated during the October 2 and 5, 2012 telephone conferences and set forth below, Defendants' application to amend their invalidity contentions is **DENIED**.

I. BACKGROUND

On April 8, 2011, Plaintiffs commenced the action at Docket Number 11-cv-1997 ("First Action") asserting ownership of U.S. Patent Nos. 6,974,595 ("'595 patent"), 7,482,377 ("'377 patent") and 7,759,394 ("'394 patent") and alleging infringement due to "Defendants' filing of an Abbreviated New Drug Application ('ANDA') No. 20-2430 seeking approval to sell diclofenac potassium for oral solution 50 mg prior to the expiration of the patents-in-suit, which are assigned to and/or exclusively licensed by Plaintiffs and listed in the publication entitled 'Orange Book: *Approved Drug Products Therapeutic Equivalents*.'" (Dkt. No. 1, ¶¶ 9-10). On July 22, 2011, pursuant to the pretrial scheduling order (Dkt. No. 33) in the First Action, Defendants served their invalidity contentions against the '595 patent, the '377 patent and the '394 patent in the in the First Action ("First Contentions"). (Joint Letter, p. 2; 6). Discovery ensued, with

[1] Docket Number 89 refers only to Defendants' October 19th Submission. Plaintiffs' submission was not filed via CM/ECF.

Plaintiffs making an initial production of documents on September 6, 2011. (Id., p. 6; Dkt. 33).

Then, after U.S. Patent No. 8,097,651 ("'651 patent") issued on January 17, 2012, Plaintiffs filed a second action on February 27, 2012 at Docket Number 12-cv-1243 asserting the '651 patent and alleging infringement by Defendants ("Second Action"). (Dkt. No. 1; see also Joint Letter, p. 6). Defendants served their invalidity contentions in the Second Action on March 13, 2012 ("Second Contentions"). (Dkt. No. 5 in Second Action; Dkt. No. 58 in First Action; Joint Letter, p. 6). Despite asserting new invalidity theories in the Second Contentions at the outset of the Second Action, Defendants did not, at that time, amend their First Contentions to incorporate the new theories. (Joint Letter, p. 6).

In the September 6th Letter to the Court, Defendants addressed amending their invalidity contentions in the First Action to add: (1) "an indefiniteness defense pursuant to 35 U.S.C. § 112 ¶ 1;"[2] (2) "prior art-based invalidity contentions to Plaintiffs' newly asserted '651 patent [in the Second Action], based upon prior art that Wockhardt previously identified to Plaintiffs with respect to the original patents in suit;" and (3) "a printed publication defense relating to a product sold in Egypt before January 2004" referred to as Catafast Egypt. (Dkt. No. 74).

II. LEGAL STANDARD

Local Patent Rule 3.7 ("Rule 3.7") governs "[a]mendments of any contentions, disclosures, or other documents required to be filed or exchanged . . ." See also Jazz Pharm., Inc. v. Roxane Labs., Inc., 2012 U.S. Dist. LEXIS 107408, at *6 (D.N.J. July 30,

[2] All of Defendants later submissions (and Plaintiffs for that matter) refer to 35 U.S.C. § 112 ¶ 2, therefore the reference to ¶ 1 in the September 6th Letter is presumably in error.

2012). Pursuant to Rule 3.7, a party moving for leave to amend its invalidity contentions may do so only "by order of the Court upon a timely application and showing of good cause." Rule 3.7; see also King Pharm., Inc. v. Sandoz, Inc., Civ. Action No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010); Jazz Pharm., Inc., 2012 U.S. Dist. LEXIS 107408, at *6.

Rule 3.7 sets forth a "[n]on-exhaustive" list of "examples of circumstances that may, absent undue prejudice to the adverse party, support a finding of good cause[.]" Rule 3.7. "While non-exhaustive, the list of circumstances included in [Rule 3.7] establishes that a dominant consideration in determining whether good cause exists to permit a requested amendment is the diligence of the moving party." AstraZeneca AB v. Hanmi USA, Inc., 2011 WL 5526009, at *4 (D.N.J. Nov. 14, 2011). In conducting a good cause analysis, the court "considers first whether the moving part was diligent in amending its contentions and then whether the non-moving part would suffer prejudice if the motion to amend were granted." Acer, Inc. v. Tec. Props. Ltd., Nos. Civ. No. 08-00877, 08-00882, 08-05398, 2010 WL 3618687, at *4 (N.D.Cal. Sep.10, 2010). Thus, Rule 3.7 permits amendments provided the following three elements are established: (1) timely application to the court; (2) good cause for the amendment; and (3) no undue prejudice to the adverse party. Jazz Pharm., Inc., 2012 U.S. Dist. LEXIS 107408, at *6.

The local patent rules governing contentions "are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." TFH Publ'ns, Inc. v. Doskocil Mfg. Co., Inc., 705 F. Supp. 2d 361, 365–66 (D.N.J. 2010) (internal quotation omitted); see O2 Micro Int'l Ltd., 467 F.3d at 1366 n.12. They "seek to balance the right to develop new information in

discovery with the need for certainty as to legal theories." O2 Micro Int'l Ltd., 467 F.3d at 1366. Accordingly, motions to amend invalidity contentions are not granted as liberally as motions to amend pleadings outside of the patent litigation context, partly because "the philosophy behind amending claim charts is decidedly conservative and designed to prevent the 'shifting sands' approach," to a party's contentions. TFH Publ'ns, Inc., 705 F. Supp. 2d at 366; cf. Fed. R. Civ. P. 15(a)(2). Sufficiently satisfying the elements set forth in Rule 3.7 is not a simple undertaking, and requires the movant to overcome a substantial preference against granting the amendment. See, e.g., O2 Micro Int'l Ltd., 467 F.3d at 1367-68 (holding that invalidity contentions are not easily amended because the rules are intended to ensure the parties establish theories of the case early in litigation and adhere to them throughout); Jazz Pharm., Inc., 2012 U.S. Dist. LEXIS 107408, at *6-9; King Pharm. Inc., 2010 WL 2015258, at *7.

III. DISCUSSION

A. *Defendants' Proposed Amendment to Include Prior Art References*

In the instant application, Defendants seek to amend their First Contentions in the First Action to incorporate four new prior art references that were included in the Second Contentions served on March 13, 2012 in the Second Action. (Dkt. No. 89, p. 2). First, the Court determines whether this application is timely. Rule 3.7's requirement of timely application to amend ensures that the Rules are impactful in shaping the litigation. O2 Micro Int'l Ltd., 467 F.3d at 1366 ("If the parties were not required to amend their contentions promptly after discovering new information, the contentions requirement would be virtually meaningless"). Thus, where the movant is aware of the need to amend its invalidity contentions, yet needlessly delays making application to the court, the

purpose of the Local Patent Rules in fashioning the conduct of discovery in anticipation of trial is frustrated. Id. Accordingly, untimely application to the court for leave to amend can be grounds for denial of the motion. Rule 3.7; see, e.g., O2 Micro Int'l Ltd., 467 F.3d at 1367–68 (holding delay of three months, absent good cause, was unreasonable); Jazz Pharm., Inc., 2012 U.S. Dist. LEXIS 107408, at *5 (holding that five month delay, absent good cause, was unreasonable). But cf. TFH Publ'ns, Inc., 705 F. Supp. 2d at 367 ("[T]wo months is [not] an inordinate amount of time to give notice of one's intent to amend its infringement contentions, especially given the current stage of this case.").

Here, the Court finds that Defendants' application to incorporate the four new prior art references into the First Contentions is untimely. Liberally construed, the latest date the Court may presume that the Defendants became aware of these new theories was March 13, 2012, the day Defendants served the Second Contentions that included these new theories. (Dkt No. 89, p. 2). However, Defendants did not make, let alone notify the Court of, the instant application for leave to amend until six months later in the September 6th Letter. (Dkt. No. 74). Waiting this length of time does not constitute timely application as required by Rule 3.7. See, e.g., O2 Micro Int'l Ltd., 467 F.3d at 1367-8; Jazz Pharm., Inc., 2012 U.S. Dist. LEXIS 107408, at *5.

The absence of timely application may be ameliorated by the satisfaction of the second element, a demonstration of good cause.[3] See O2 Micro Int'l Ltd., 467 F.3d at

[3] It is worth noting that, although the elements of timely application and good cause under Rule 3.7 analysis coalesce, the timely application element may also independently justify grounds for denial of a motion to amend invalidity contentions, irrespective of the presence of good cause. One can imagine a situation in which good cause is present, yet a party nonetheless needlessly delays making application to the court for an amendment. In such situations, the court would certainly be within its authority to deny the motion. See Rule 3.7 ("Amendment of any contentions . . . may be made only by order of the Court upon a timely application and showing of good cause") (emphasis added).

1366. Establishing good cause "requires a showing of diligence." Id. "The burden is on the movant to establish diligence rather than on the opposing party to establish a lack of diligence." Id. Thus, to satisfy the good cause element, a party must demonstrate that it acted diligently in discovering the basis of the proposed amendment. Id. at 1367-68. In addition to diligence, in determining the existence of good cause courts consider prejudice to the opposing party. AstraZeneca AB, 2011 U.S. Dist. LEXIS 130980, at *12.

Defendants assert that good cause exists for their amendment because they were "diligent in [their] search for and disclosure of recently discovered material prior art." (Joint Letter, p. 3). To support their claim of diligence, Defendants state, *inter alia*, that: (i) they "conducted a prior art search . . ." which included "a review of a variety of articles, patents, and patent publications. However, despite diligent searching, the four new references were not initially identified" (Dkt. No. 89, p. 2); (ii) in preparation of the Second Contentions in the Second Action, they "included both prior art from [their] original contentions *and* new prior art [they] discovered as a result of subsequent searching . . . after '651 patent issued;" (iii) "[a]lthough [they] did not explicitly state that the new references cited in [their] second contentions should be applied against the '595, '377 and '394 patents, it was [their] intent and should have been apparent to Plaintiffs given the overlapping subject matter of the two lawsuits;" (iv) their "first contentions actually included language incorporating many of the references [they] now seek to include from its second contentions;" and (v) they considered the Second Contentions to supplement the First Contentions. (Joint Letter, p. 3; see also Dkt. No. 89, p. 2-3).

The Court finds that Defendants' have not met their burden of establishing good cause. Rule 3.7 states that good cause may be shown by "recent discovery of material prior art despite earlier diligent search." Rule 3.7. Despite Defendants statement that they "diligent[ly] search[ed]" (Dkt. No. 89, p. 2), Defendants have provided no explanation as to why they waited the six months from service of their Second Contentions to even raise a proposed amendment with the Court. The good cause requirement of Rule 3.7 dictates "a showing that the party seeking leave to amend acted with diligence in promptly moving to amend when new evidence is revealed." O2 Micro Int'l Ltd., 467 F.3d at 1363. That is not the case here. See, e.g., id. at 1367-68 (stating that unsubstantiated need to digest and marshal evidence not sufficient to constitute diligence); Jazz Pharm., Inc., 2012 U.S. Dist. LEXIS 107408, at *5 (holding that five month period did not demonstrate diligence); King Pharm., Inc., 2010 WL 2015258, at *4 (finding movant's eighteen-month delay in realizing the materiality of documents in its possession demonstrated lack of diligence); West v. Jewelry Innovations, Inc., 2008 U.S. Dist. LEXIS 84928, at *11, (N.D. Cal. Oct. 8, 2008) (noting that "an inadvertent omission does not establish diligence").

Furthermore, merely including language in the Second Contentions that supposedly incorporates the four new prior art references into the First Contentions does not comport with Rule 3.7, which exists, in part, to "provide all parties with adequate notice and information with which to litigate their case." Jazz Pharm., Inc., 2012 U.S. Dist. LEXIS 107408, at *6 (internal quotations omitted). The indirect nature of Defendants' incorporation-by-reference theory does not amount to a form of notice that adequately "crystallize[s the] . . . theories of the case." TFH Publ'ns, Inc., 705 F. Supp.

2d at 366 (internal quotations omitted). Indeed, permitting such a form of notice would embrace, rather than repudiate, the "'shifting sands' approach" to the formulation of invalidity contentions, which is explicitly contrary to the intention of Rule 3.7 and wholly unsupported by case law. See Rule 3.7; O2 Micro Int'l Ltd., 467 F.3d at 1364; TFH Publ'ns, Inc., 705 F. Supp. 2d at 366.

Most detrimental to Defendants' demonstration of good cause, however, is the lack of consistency in its arguments. On one hand, Defendants argue that, "despite diligent searching, the four new references were not initially identified" at the time it finalized the First Contentions in July 2011 (Dkt. No. 89), but rather, were uncovered upon "subsequent searching it conducted after [*sic*] '651 patent issued on January 17, 2012." (Joint Letter, p. 3). Yet on the other hand, Defendants argue that its "first contentions included language incorporating many of the references [Defendants] now seek[] to include from its second contentions." (Id.). This Court is not persuaded that the Defendants could reasonably claim they acted diligently where they were both unaware of the new references at the time they finalized the First Contentions (Dkt. No. 89, p. 2), yet still include language incorporating them into its First Contentions. (Joint Letter, p. 3). Certainly, if the Defendants had enough information to include language that incorporated the new references into the First Contentions, then the Defendants must have had enough information in their possession to actually assert the new references in the First Contentions. But neither the failure to recognize the materiality of information in one's possession, nor an inadvertent omission, is a demonstration of diligence. King Pharm., Inc., 2010 WL 2015258, at *4 ("Waiting approximately 18 months to appreciate the materiality of the publication" was not a demonstration of diligence); West, 2008 U.S.

Dist. LEXIS 84928, at *11 ("inadvertence is hardly the same as diligence"). Accordingly, because the Court finds that the Defendants did not act diligently in uncovering and disclosing the new references, the Defendants lack good cause in seeking the motion to amend.

Finally, as to the undue prejudice prong, the Federal Circuit has made it clear that the Court only considers undue prejudice if the moving party's application was both timely and satisfies the good cause requirement of Rule 3.7. O2 Micro, 467 F.3d at 1368; see also Jazz Pharm., Inc., 2012 U.S. Dist. LEXIS 107408, at *22. However, courts in this district have addressed prejudice "where the movant has proffered a reason, albeit unpersuasive, for the untimeliness of the application and/or failure to illustrate good cause." Jazz Pharm., Inc., 2012 U.S. Dist. LEXIS 107408, at *22; see also King Pharm., Inc., 2010 WL 2015258, at *4. Therefore, in determining whether leave to amend would impose undue prejudice to the non-movant, courts consider "whether permitting the proposed amendments would (1) require [the non-movant] to expend significant additional resources, or (2) significantly delay the resolution of the dispute." TFH Publ'ns, Inc., 705 F. Supp. 2d at 367. As to the first factor, if granting the amendment would cause the non-movant to expend significant financial resources, thereby unduly prejudicing the non-movant, then granting leave to amend is inappropriate. See id. As to the second factor, courts consider the "stage of litigation and the impact of permitting an amendment on the non-moving party's trial strategy." Jazz Pharm., Inc., 2012 U.S. Dist. LEXIS 107408, at *5. Relevant to this inquiry is "the due date for filing of Invalidity Contentions, the due date of opening and responsive Markman briefs, and the date of the application." Id.

Defendants claim that no undue prejudice will be imposed on Plaintiffs because they "will be required to litigate the references regardless of the outcome" of the instant application, and inclusion of the new references will not require Plaintiffs to expend additional resources or delay the resolution of the dispute. (Dkt. No. 89, p. 3). Moreover, Defendants assert that since "Plaintiffs were aware of the four new prior art references in the [Second Contentions]" they "have had ample opportunity during fact discovery to seek discovery related to these four references." (Id., p. 4). Further, Defendants maintain that the addition of the new references to the First Contentions will not delay the litigation because the Markman hearings have not occurred yet, claim construction will not be affected, and because Plaintiffs had the opportunity to conduct fact discovery relating to these new references since the time it finalized the Second Contentions in March 2012. (Id.).

This Court also finds these arguments unpersuasive and that the proposed amendment would be prejudicial to Plaintiffs. At the time Defendants revealed their intent to amend their First Contentions, fact discovery was nearing its end and claim construction issues had been briefed, thus the case was no longer in its early stages. See King Pharm., Inc., 2010 WL 2015258, at *5; Jazz Pharm., Inc., 2012 U.S. Dist. LEXIS 107408, at *23. Moreover, at the time of the instant application, Plaintiffs had not had the opportunity to conduct discovery on the new references as they relate to the three patents-in-suit in the First Action, two of which, as noted by Plaintiffs, "are not related to the '651 patent and have significantly different claims and patent specification." (Plaintiffs' October 19th Submission, p. 4). Thus, an amendment would require additional discovery and unreasonably delay the action. See King Pharm., Inc., 2010 WL

2015258, at *5; Jazz Pharm., Inc., 2012 U.S. Dist. LEXIS 107408, at *23. Additionally, if the amendment was permitted, Plaintiffs would likely be required to reevaluate their strategy developed over the course of the last sixteen-months as it relates to the '595, '377, and '394 patents in order to account for the New Contentions. Jazz Pharm., Inc., 2012 U.S. Dist. LEXIS 107408, at *23; see also Plaintiffs' October 19th Submission, p. 4. Plaintiffs will be required to expend significant resources in analyzing the new references and evaluating how to structure their case in light of the inclusion thereof, all the while delaying the resolution of this dispute.

Accordingly, Defendants application to amend their First Contentions to incorporate new prior art references is denied.

B. *Defendants' Proposed Amendment to Include Claim of Indefiniteness Under 35 U.S.C. § 112 ¶ 2*

Defendants also seek to amend the First Contentions to include a defense of indefiniteness under 35 U.S.C. § 112 ¶ 2. (Joint Letter, p. 3-4). In support of Defendants assertion that good cause exists, Defendants aver that they became aware of claim terms that were not amenable to construction as early as February 25, 2012, and "hoped that construction of these terms could be resolved through the meet and confer process with Plaintiffs." (Joint Letter, p. 3). At some point before June 25, 2012, Defendants "realized the potential need to formally assert a defense of indefiniteness[,]" but took no action with respect to amending their invalidity contentions until September 6, 2012. (Id., p. 3-4). Defendants attribute this delay to "Plaintiffs urgings" that the Markman hearings were "not the proper forum for indefiniteness." (Id., p. 4). Further, Defendants argue that granting leave to amend will not prejudice Plaintiffs because "ample time remains for [fact and expert] discovery." (Id.).

However, the Court finds that Defendants were not timely in seeking to amend their invalidity contentions to incorporate the indefiniteness defense. Defendants were admittedly aware of the potential need to amend their invalidity contentions to assert a defense of indefiniteness in February 2012 and should have absolutely been aware that the need to amend existed by June after four months of attempting to resolve the construction of the claim terms proved futile. (Joint Letter, p. 3-4). Waiting until August or September to raise this proposed amendment to their invalidity contentions after being aware of the need to do so for such a period frustrates the purpose of the Local Patent Rules in shaping discovery. See O2 Micro Int'l Ltd., 467 F.3d at 1366; Jazz Pharm., Inc., 2012 U.S. Dist. LEXIS 107408, at *5. Accordingly, the Court finds Defendants' application untimely.

Nonetheless, even if its application had been timely, Defendants have not met their burden of demonstrating good cause. Defendants assertions that they found certain claim terms ambiguous during the claim construction process does not establish that they acted diligently in discovering such ambiguities. (Joint Letter, p. 3). Defendants seek to shift the blame to Plaintiffs for their failures where they offer, as the only explanation for their lack of amendment to add a defense of indefiniteness, that Plaintiffs "urged" them to postpone the issue. (Id., p. 3-4). Certainly, Defendants are responsible for their own actions in this litigation. Moreover, the Local Patent Rules' goal of "crystallizing" parties' theories early in the case would be obliterated if a party could amend its contentions upon uncovering defenses during discovery that could have been discovered prior to filing its invalidity contentions. See TFH Publ'ns, Inc., 705 F. Supp. 2d at 366. Diligence does not exist where Defendants uncover the basis of an invalidity defense

during the claim construction process if they could have done so prior to filing their invalidity contentions. See O2 Micro Int'l Ltd., 467 F.3d at 1367–68. Thus, by failing to sufficiently explain why they were unable to uncover, despite diligent efforts to do so, the defense of indefiniteness prior to submitting their contentions, Defendants fail to carry their burden of demonstrating that they acted diligently. See id.

And, for the same reasons as set forth above, granting Defendants leave to amend would prejudice Plaintiffs. Accordingly, Defendants application to amend their invalidity contentions to add an indefiniteness defense under 35 U.S.C. § 112 ¶ 2 is denied.

C. *Amendment to Include Material Art Relating to Catafast Egypt*

Lastly, Defendants seek leave to amend their invalidity contentions to include prior art relating to Catafast Egypt. (Dkt. No. 74; Joint Letter, p 5). Specifically, Defendants claim that "[w]hile conducting a systematic review of Plaintiffs' voluminous document production . . . counsel for [Defendants] discovered a string of highly relevant emails on or around August 5, 2012" relating to Catafast Egypt that "would qualify either as invalidating prior art . . . or as prior art references." (Joint Letter, p. 5). Despite receiving Plaintiffs first production of documents almost a year earlier on September 6, 2011 (id., p. 7), Defendants assert that they were timely and diligent because "the relevant information was buried amongst the nearly 1.3 million pages of documents," and they "notified Plaintiffs of [their] intent to amend [their] contentions on August 14, 2012 within 10 days of discovering [the materials]." (Id.).

Plaintiffs argue, *inter alia*, that Defendants were on notice of "the sale of Catafast Egypt by Novartis from the very first set of documents produced on September 6, 2011." (Joint Letter, p. 7). Plaintiffs maintain that this initial production included "a finalized

licensing agreement between APR and Novartis relating to the sale by Novartis of a diclofenac sachet in Egypt ('Catafast Egypt')" and that "that document specifically references the launch by Novartis of Catafast Egypt in January 2004." (Id.). Further, Plaintiffs state that the other document relied on by Defendants in their proposed amendments was produced in April 2012, thus Defendants "should not benefit from having sat on a document in its possession for that many months." (Id.).

The Court agrees with Plaintiffs and finds that Defendants fail to meet their burden of establishing that they acted with diligence. Simply declaring that the review of such voluminous discovery "does not happen overnight" does nothing to demonstrate that Defendants acted with diligence in discovering documents they had in their possession for nearly a year or at the very least five months. (Joint Letter, p. 5, 7); see also King Pharm., Inc., 2010 U.S. Dis. LEXIS 50163, at *12. In King Pharm., Inc., the Court found that the movant's failure to appreciate the materiality of discovery documents in its possession for eighteen-months did not constitute good cause. Id. The court reasoned that the movant's claim of acting diligently was undermined by the length of time it took to realize the materiality of the documents. Id. Likewise, in West, the court rejected the movant's excuse of inadvertence as constituting good cause. 2008 U.S. Dist. LEXIS 84928, at *11. There the Court held that "carelessness is not compatible with a finding of diligence and offers no reason for a grant of relief." Id. at *11–12. Therefore, inadvertence can in no way constitute good cause. Because Defendants fail to provide an adequate explanation as to why they did not discover the information sooner, the Court finds that Defendants have not met their burden of demonstrating diligence, and therefore, are lacking good cause.

Furthermore, the Court finds that Plaintiffs would be significantly prejudiced if Defendants were granted leave to amend. Permitting Defendants to amend their invalidity contentions would cause Plaintiffs to expend significant financial resources in order to refute the validity of the alleged prior art. (Joint Letter, p. 8). Considering the prior art relates to the release of a drug in Egypt by a third party licensee located in Europe, it is likely that the resolution of this issue would require extensive and costly third party discovery. (Id.). Nevertheless, even if all of the relevant discovery and information was located in the United States, requiring Plaintiffs to defend against this contention would still impose a substantial financial burden which would be prejudicial to Plaintiffs. See TFH Publ'ns, Inc., 705 F. Supp. 2d at 367.

Accordingly, Defendants application to amend their invalidity contentions to add prior art relating to Catafast Egypt is denied.

IV. CONCLUSION

For the reasons set forth above, Defendants' application to amend their invalidity contentions is hereby **DENIED.**

SO ORDERED.

s/ Cathy L. Waldor
CATHY L. WALDOR
UNITED STATES MAGISTRATE JUDGE

DATED: January 23, 2012